Application No.: 09/613,707

Docket No.: HO-P02004US0

#### **REMARKS**

Claims 5-8 and 11-12 are pending in this application. Applicants have canceled claims 6 and 12 and amended claims 5 and 11 without prejudice and acquiescence. Applicants maintain the right to pursue the canceled claims in a divisional application. Support for the amendment can be found in the Specification on page 5, lines 5-6. Applicants also have amended the Specification on page 5, lines 1-5 to delete a typographical error. Applicants have enclosed as Appendix A a marked version of the claims illustrating the amendments contained herein and a marked version of the amended paragraph. For the convenience of the Examiner, Applicants have also enclosed in Appendix B a copy of all pending claims containing the amendments herein. Applicants assert that no new matter is added.

The issues outstanding in this application are as follows:

- The specification has been objected as the Office Action alleges that Applicants have not meet the conditions of the Budapest Treaty.
- Claims 5 and 11 have been rejected under 35 U.S.C. §103(c), which the Office Action alleges that the claimed subject matter is obvious by Dran et al.

Applicants respectfully traverse the outstanding rejections and objections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

## A. The Specification meets all requirements.

The Action has objected to the Specification because the Office Action alleges that Applicants have not meet the conditions of the Budapest Treaty. Applicants traverse.

Applicants enclose herewith notification from the ATCC indicating the deposition of the biological material. Yet further, in the previous response filed on March 18, 2002, Applicants amended the Specification to recite the name and address of the depository and the dates of the deposit. Thus, Applicants assert that all requirements have been meet under the Budapest Treaty and respectfully request withdrawal of the rejection.

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#### B. Claims 5 and 11 are not anticipated.

Claims 5 and 11 have been rejected under U.S.C. § 103(c), which the Office Action alleges that the claimed subject matter is obvious by Duran et al. Applicants respectfully traverse.

Applicants assert that there is a distinct difference between a primary cell culture and the cell line of the present invention. The primary cell culture of Dran et al., has a lifespan of about two weeks. The cell lines of the present invention are immortal.

However, in order to advance the prosecution of the present application, Applicants have amended claims 5 and 11 to recite the ATCC accession number of the cell line of the present invention. In light of this amendment, Applicants respectfully request withdrawal of the rejection.

#### C. Review of Restriction Requirement or Waive of Election

Applicants respectfully request that the Examiner review the previous Restriction Requirement that was issued on September 17, 2001. The Restriction Requirement required Applicants to choose one of the four cell lines of the present invention. Applicants assert that all four cell lines express progesterone and estrogen receptors and thus should be prosecuted together on their merits.

Applicants raised this issue with the Examiner during a telephone conference on September 18, 2002. Although the Examiner indicated that Restriction Requirement was final, Applicants believe that the Restriction Requirement was improper and respectfully request the Examiner to reexamine the Restriction Requirement and to withdraw the election. See MPEP § 811.03.

If the Examiner views the Restriction Requirement to be proper, then Applicants request that the Office waive election and permit a shift from claiming one invention to claiming another invention. Applicants are requesting that they be allowed to prosecute claims containing a Markush group having all four cell lines as indicated in Appendix C instead claims containing only one cell line, as currently pending. Applicants contend that shifting the scope of the claims from one cell line to four cell lines would result in no

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additional work or expanse for the Examiner and if anything may reduce work by simplifying

the issues, such additional applications for each cell line. See MPEP § 819.01.

Thus, Applicants are submitting herewith as Appendix C, a set of claims that are to be

prosecuted on their merits if the Examiner either removes the Restriction Requirement or

waives the election.

**CONCLUSION** 

Claims 5-8 and 11-12 are pending in this application. Claims 6 and 12 have been

canceled and claims 5 and 11 have been amended without prejudice and acquiescence.

In view of the above, each of the presently pending claims in this application is

believed to be in immediate condition for allowance. Accordingly, the Examiner is

respectfully requested to withdraw the outstanding rejection of the claims and to pass this

application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please

charge our Deposit Account No. 06-2375, under Order No. HO-P02004US0 from which the

undersigned is authorized to draw.

Dated: September 18, 2002

Respectfully submitted,

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Appendix A
Version With Markings to Show Changes Made

#### In the Specification:

The present invention also relates to a mouse mammary adenocarcinoma cell line MC7-L1 which is derived from the murine progestin-independent C7-HI tumor, wherein the cell line expresses ER and PR and is deposited with the have been deposited on October 28, 1999 with American Type Culture Collection (ATCC), 1081 University Blvd, Manassas, Virginia 20110-2209 ATCC as Accession number PTA-890.

- 5. (Amended) A non transgenic mouse mammary adenocarcinoma cell line derived from a murine progestin-independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors and the cell line is MC7-L1 (ATCC # PTA-890).
- 11. (Amended) A kit for determining the effect of a hormone, anti-hormone, pharmacological compounds and environmental agents, wherein the kit comprises an aliquot, a MC7-L1 cell line (ATCC# PTA-890), and a method for evaluating the proliferation of cells.

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# Appendix B Claims Pending as of September 18, 2002

5. A non transgenic mouse mammary adenocarcinoma cell line derived from a murine progestin-independent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors and the cell line is MC7-L1 (ATCC # PTA-890).

- 7. A non-transgenic mouse mammary adenocarcinoma cell line system for testing the activity of a hormone, an anti-hormone, a pharmacological compound and an environmental agent, wherein the system comprises a MC7-L1 cell line.
- 8. An *in vitro* method for testing the activity of a hormone, an anti-hormone, a pharmacological compound or an environmental agent, comprising the steps of:

cultivating a cell line system, wherein the cell line system comprises

a MC7-L1 cell line derived from a murine progestinindependent C7-HI tumor, wherein the cell line expresses estrogen and progesterone receptors;

exposing the cell line system to the hormone, the anti-hormone, the pharmacological compound, or the environmental agent; and

quantifying cell proliferation.

11. A kit for determining the effect of a hormone, anti-hormone, pharmacological compounds and environmental agents, wherein the kit comprises an aliquot, a MC7-L1 cell line (ATCC# PTA-890), and a method for evaluating the proliferation of cells.

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Appendix C

### Claims if Restriction Requirement is Withdrawn

13. A non transgenic mouse mammary adenocarcinoma cell line, wherein the cell line expresses estrogen and progesterone receptors and the cell line is selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890).

- 7. A non-transgenic mouse mammary adenocarcinoma cell line system for testing the activity of a hormone, an anti-hormone, a pharmacological compound and an environmental agent, wherein the system comprises a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890).
- 8. An *in vitro* method for testing the activity of a hormone, an anti-hormone, a pharmacological compound or an environmental agent, comprising the steps of:

cultivating a cell line system, wherein the cell line system comprises

a cell line that expresses estrogen and progesterone receptors, wherein the cell line is selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890);

exposing the cell line system to the hormone, the anti-hormone, the pharmacological compound, or the environmental agent; and

quantifying cell proliferation.

11. A kit for determining the effect of a hormone, anti-hormone, pharmacological compounds and environmental agents, wherein the kit comprises an aliquot, a cell line selected from the group consisting of MC4-L1 (ATCC# PTA-889), MC4-L3 (ATCC# PTA-

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891), MC4-L2 (ATCC# PTA-892) and MC7-L1 (ATCC # PTA-890), and a method for evaluating the proliferation of cells.